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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/932,227	09/17/97	FOSSEL	E

IM11/1120

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EXAMINER	
MULLIS,J	
ART UNIT	**PAPER NUMBER**
1711	6

DATE MAILED: 11/20/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 6

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 33-60 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 33-60 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☑ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

★ U.S. GPO: 1996-410-238/40050

All remaining rejections and/or objections follow.

Claims 33-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

It is not clear whether or not the materials in claim 39 and claim 47, etc. are meant to be used as alternatives or in combination since this is not stated in the claim.

It is not clear if the "concentration of ionic salt sufficient to create an anionic environment which causes a substance to migrate from the vehicle to the skin" embraces zero concentrations of salt in that there is no reason why nitric oxide releasing substances cannot be absorbed by the skin even in the absence of salt.

Claims 35-38, 44 and 53-55 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. There is nothing in the specification which discloses a combination of a hydrophobic delivery vehicle and an ionic salt. Note in this regard page 7 of the specification discloses that "alternatively a hostile biophysical environment may be created by placing the highly charged L-arginine in an hydrophobic, oily environment such as in an oil-based cream containing little or no water. It is therefore clear that use of the hydrophobic vehicle is an alternative to the salt containing vehicles. Any claims

reciting the limitation containing a hydrophobic delivery vehicle in combination with an ionic salt therefore lack support in the specification as filed and such a limitation is new matter. Furthermore, salts in general are not soluble in hydrophobic delivery vehicles and it is therefore not clear how the method of for instance claim 35 could be conducted which is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33-34, 38, 39, 51-54, 56, 59 and 60 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Weuffen et al. (USP 5,629,002).

Weuffen et al. disclose a process in which an arginine containing substance in combination with various salts are applied to the scalp to promote hair growth, a known result of application of a nitric oxide releasing substance to the scalp. Note Example 10 in this regard and that the hair pack, embraced by applicants' "transdermal patch" may be used.

When the reference discloses all the limitations of a claim except a property or function, and the Examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention, basis exists for shifting the burden of proof to applicant. Note In re Fitzgerald et al. 619 F. 2d 67, 70, 205 USPQ 594, 596, (CCPA 1980). See MPEP § 2112-2112.02.

Claims 33-34 and 39 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hechtman (USP 5,595,753).

Hechtman discloses a "topical treatment" in which L-arginine is applied to an area being treated whereby nitric oxide is released. Note the Abstract and the paragraph bridging columns 1

and 2. Note that an electrolyte solution may be used in patent claim 6.

As the reference discloses all the limitations of the claims except for applicant's function it is applicants burden to prove that the function is not inherent in the reference.

Applicants' remarks are moot since all previous rejections and/or objections have been withdrawn. The withdrawal of the previous rejections based on the prior art is based on the assumption that applicants' claims do not embrace a non-zero quantity of salt.

It is noted that applicants have argued that "In fact, none of the prior art cited by the Examiner includes the use of a hostile biophysical environment". However such an environment appears to be inherent in the art relied upon above in that an ionic salt is present and in that absorption of the nitric oxide releasing substance by the skin is explicitly disclosed to be inherent. In any case, the term "hostile biophysical environment" does not appear in the claims nor is it clear what a hostile biophysical environment might embrace.

This Office action is not being made FINAL.

Any inquiry concerning this communication should be directed to Jeffrey Mullis at telephone number (703) 308-2820.

J. Mullis:cdc

November 19, 1998

JEFFREY C. MULLIS
PRIMARY EXAMINER
GROUP ~~1200~~ 1711